

REMARKS

By this Amendment, the Specification and Drawings have been amended to correct typographical errors, provide for consistent numbering of elements depicted in the drawings and referred to in the Specification, and to add drawings from a parent provisional application which were inadvertently left out of the current application as filed. No new matter is added by the amendments to the Specification and Drawings.

By this Amendment, claims 21, 22, 25, 33, 34, 35, 45, 55, 63, 64, and 69 have been amended, including the recitation of a rigid material, the use of an electrical heater or resistive heater, etc. The amendments are supported throughout the application as originally filed, including at page 93, lines 27-38; page 104, lines 11-14; etc.

Claims 29, 38-40, 46-51, 54, 59, 60, 62, and 65-68 have been cancelled.

New claims 70-85 have been added. New claims 70-85 are supported throughout the application as originally filed. For example, independent claims 70 and 79 each recite a rapid electrical heater embedded in the intermediate material, as discussed at page 62, lines 27-31; page 93, lines 27-38, etc., of the application as originally filed.

No new matter is added by the claim amendments and/or new claims.

Claims 21-23, 25, 33-35, 45, 55, 57, 58, 61, 63, 64, and 69-85 are now pending.

The Objection to the Substitute Specification:

The Examiner objected to the Substitute Specification filed October 1, 2008 as not being in conformance with 1.125(c) as there was allegedly not a marked-up copy of the specification indicating the changes thereto. Applicant notes that marked-up pages of the Specification were submitted, which indicated all changes to the Specification, but that the Marked-Up Copy of the Specification was not a complete copy with all pages of the Specification.

By this Amendment, a Substitute Specification is submitted, in Clean and Marked-Up versions, with both versions including all pages of the Specification.

The Objection to the Drawings:

The Examiner objected to the drawings as having “none of the elements labeled with indicia indicative of their function.” Applicant notes that the Replacement Sheets submitted in the Amendment of October 1, 2008 included corrected numberings, etc. The current

amendments to the Specification, and the Substitute Specification submitted herewith, provide the appropriate corresponding references to the elements. Accordingly, the Drawings are believed to be in appropriate form.

The Examiner further objected to the drawings as not showing every feature specified in the claims, namely a “generally solid absorbing material” and a “device sized and configured to be held in the hand.” This objection is not understood. There is no recitation in the claims of a “generally solid absorbing material.” Moreover, the phrase “device sized and configured to be held in the hand,” was expressly dropped from the claims (and replaced with the original “handpiece” language) in the Amendment dated October 1, 2008.

Reconsideration of the Objection to the Drawings is respectfully requested.

The Objection to the Amendments:

The Examiner objected to the amendments filed Feb. 11, 2009; Oct. 1, 2008; Jan. 11, 2008; and April 24, 2007 under 35 USC 132(a) as introducing new matter into the disclosure. More specifically, the Examiner alleged that the following material constituted new matter:

“a system for enhancing or improving the transcutaneous or transdermal delivery of various topical substances, chemicals, or drugs”;

“to prevent any emitted energy from reaching the target area of the skin without being absorbed by the intermediate substance”; and

“without removing skin tissue from the target area.”

Applicant believes that support exists in the application as originally filed for all of the above material. However, to move forward the prosecution of this application, the current Amendment removes all references to: “without removing skin tissue from the target area.”

As to the phrase “to prevent any emitted energy from reaching the target area of the skin without being absorbed by the intermediate substance,” Applicant notes that there is support for this language in the specification as originally filed. Namely, at page 62, line 9 to page 63, line 32 of the originally-filed specification (i.e., paras. 0377-0381 of the application as published), the device is described as converting energy (e.g., electric or optical) into thermal energy which is delivered to the skin, and is further described as providing “no exposure of the skin to photons or any energy other than [sic] highly controlled thermal energy.” See page 63, lines 28-30 of the originally-filed specification (i.e., para. 0381 as published). Accordingly, the device clearly

prevents any emitted (i.e., non-thermal) energy from reaching the target skin except in the thermal form created when the emitted (non-thermal) energy is absorbed by the intermediate substance. However, the issue is believed somewhat moot as the limitation and associated language have been deleted from the claims by this Amendment. However, note that claim 34 has been amended to recite that the device is configured to prevent any energy from the device except for thermal energy from contacting the target area of the skin. This language is specifically supported in the originally-filed specification, as discussed above.

As to the phrase “a system for enhancing or improving the transcutaneous or transdermal delivery of various topical substances, chemicals, or drugs,” Applicant notes that this exact phrase was included in the specification as originally filed, namely at page 33, lines 36-37 thereof (which appears in the Application as published at paragraph 0211). Further support is found at page 39, lines 3-5 of the originally-filed specification (at paragraph 0243 of the published Application), which recites “expanding a pore of the skin, and, optionally, *delivering a pharmaceutical product through the expanded pore.*” [emphasis added]. Accordingly, reconsideration of the objection to the language as being new matter is requested.

In view of the above, the claims are believed in compliance with 35 USC 112.

The 112, First Paragraph Rejections of the Claims

The Office Action rejected claims 21-23, 25, 29, 33-35, 38-40, 45-51, 54, 55, and 57-69 under 35 USC 112, first paragraph, as failing to comply with the written description requirement. More specifically, the following language was objected to as not being in the Specification:

“device sized and configured to be held in the hand”;

“thereby to enhance transdermal drug delivery”;

“to prevent any emitted energy from reaching the target area of the skin without being absorbed by the intermediate substance”; and

“without removing skin tissue from the target area.”

Applicant notes that the language “device sized and configured to be held in the hand” was expressly dropped from the claims in the Oct. 1, 2008 Amendment, and was replaced with the original language “handpiece” from the application as originally filed. Accordingly, reconsideration of the 35 USC 112 rejection is requested.

Applicant notes that the language “thereby to enhance transdermal drug delivery” is clearly supported in the specification, both in its original form and as amended. The phrase “a system for enhancing or improving the transcutaneous or transdermal delivery of various topical substances, chemicals, or drugs” was included the specification as originally filed, namely at page 33, lines 36-37 thereof (which appears in the Application as published at paragraph 0211). Further support is found at page 39, lines 3-5 of the originally-filed specification (which is at paragraph 0243 of the Application as published), which recites the invention as “expanding a pore of the skin, and, optionally, delivering a pharmaceutical product through the expanded pore.” [emphasis added]. Accordingly, reconsideration and withdrawal of the 35 USC 112 rejection based on that language is requested.

As to the phrase “to prevent any emitted energy from reaching the target area of the skin without being absorbed by the intermediate substance,” Applicant notes that there is support for this language in the specification as originally filed. Namely, at page 62, line 9 to page 63, line 32 of the originally-filed specification (i.e., paras. 0377-0381 of the application as published), the device is described as converting energy (e.g., electric or optical) into thermal energy which is delivered to the skin, and is further described as providing “no exposure of the skin to photons or any energy other than [sic] highly controlled thermal energy.” See page 63, lines 28-30 of the originally-filed specification (i.e., para. 0381 as published). Accordingly, the device clearly prevents any emitted (i.e., non-thermal) energy from reaching the target skin except in the thermal form created when the emitted (non-thermal) energy is absorbed by the intermediate substance. The issue is believed to be somewhat moot as the limitation and associated language have been deleted from the claims by this Amendment. However, note that claim 34 has been amended to recite that the device is configured to prevent any energy from the device except for thermal energy from contacting the target area of the skin. Note that this language is specifically supported in the originally-filed specification, as discussed above.

Applicant believes that support exists in the application as originally filed for the limitation “without removing skin tissue from the target area.” However, to move forward the prosecution of this application, the current Amendment removes all references to the following: “without removing skin tissue from the target area.”

In view of the above, it is believed that the claims are in compliance with 35 USC 112.

The 112, Second Paragraph Rejections of the Claims

The Office Action rejected claims 21-23, 25, 29, 33-35, 38-40, 45-51, 54, 55, and 57-69 under 35 USC 112, second paragraph, as being indefinite. More specifically, the following language was objected to as being unclear and as lacking antecedent basis in the Specification:

“to prevent any emitted energy from reaching the target area of the skin without being absorbed by the intermediate substance”; and

“without removing skin tissue from the target area.”

As discussed previously, Applicant believes that support exists in the application as originally filed for the above limitations. However, to move forward the prosecution of this application, the current Amendment removes all references to the objected-to language. However, note that claim 34 has been amended to recite the device being configured to prevent any energy from the device except thermal energy from contacting the target area of the skin. This language is specifically supported in the originally-filed specification, as discussed above.

In view of the above, it is believed that the claims are in compliance with 35 USC 112.

The 102 Rejections of the Claims over Neev ‘438

The Office Action rejected an unidentified number of claims as being anticipated under 35 USC 102(b) by Neev ‘438. More specifically, the Office Action stated the film of Neev ‘438, which is a layer applied to skin that remains on the skin during depilation, was “generally solid.”

As a first matter, Applicant notes that the actual claims anticipated have not been identified. Also, the term “generally solid” does not appear in the claims, either in their currently amended form or in the previous iteration. This in and of itself is sufficient to support Applicant’s traverse of the 102 Rejection.

The skin-covering layer of Neev ‘438 is not disclosed as being a solid layer. Moreover, all pending independent claims as currently amended include the limitation that the intermediate material comprises a layer of “rigid” material. The skin-covering layer of Neev ‘438 is clearly not rigid. Applicant further notes that Neev ‘438 requires electromagnetic energy applied directly to the skin for selective hair removal, which is in direct contrast to the current claims which provide thermal energy to the skin.

In view of the above, reconsideration of the 102 rejections of the claims is respectfully requested.

The 103 Rejections of the Claims over Neev '438 and Eppstein

The Office Action claims 21-23, 25, 29, 33-35, 38-40, 45-51, 54, and 65-69 as being obvious under 35 USC 103 over Neev '438 in view of Eppstein et al. (US 6,530,915). More specifically, the Office Action alleged that Neev '438 taught a radiation source with a highly absorbing substance not contacting the skin. The Office Action further alleged that Eppstein et al. taught a photothermal structure with an absorbing substance suspended in a carrier which is then printed on a substrate which can include agar or paper.

Applicant notes that claims 29, 38-40, 46-51, 54, and 65-68 have been cancelled without prejudice, so claims 21-23, 25, 33-35, 45, and 69 remain of the claims subject to the rejection.

Each independent claim of the application (as amended), i.e., claims 21 and 55 as well as new claims 70 and 81, recites an apparatus or method for achieving pore expansion via application of thermal energy. Thermal energy is provided to skin via an intermediate material comprising a layer of rigid material. No such teaching is present in Neev '438 or Eppstein.

Neev '438 discloses the application of electromagnetic energy (e.g., light, etc.) directly to the skin in order to permanently remove hair, etc. By contrast, the current claims as amended specify the application of thermal energy, not electromagnetic energy, to the skin. Moreover, the claims as amended recite the energy source as an electrical heater or resistive heating element. This is in contrast to Neev '438, which requires electromagnetic energy in order to achieve the selective removal of hair.

Eppstein discloses a device for ablating human skin, and more specifically a device for ablating the skin to create micropores therein in order to withdraw blood or other biological liquids. All pending claims of the current invention recite methods and/or devices for pore expansion. By contrast, in all embodiments of Eppstein, the underlying skin is ablated. See Eppstein, e.g., col. 1, lines 10-13; col. 4, lines 35-40; col. 9, lines 5-9. Thus, Eppstein addresses tissue removal, and not pore expansion. Tissue removal will not inherently cause pore expansion. The teachings of Eppstein are thus in contrast to the current claims, which specifically recite that the pores are expanded.

Eppstein further teaches a tissue-contacting layer which is a flexible and which is adhered to the skin to form a tight seal to prevent fluid leakage. See Eppstein, e.g., col. 5, lines 12-14; lines 32-36. This is in contrast to the currently claimed invention, which has an intermediate

material comprising a rigid material contacting the skin, with the tissue-contacting material disposed in a cap secured to the device.

In view of the above, claims 21-23, 25, 33-35, 45, and 69 as amended are believed allowable over the cited art.

The 103 Rejections of the Claims over Neev '438 and Eppstein and Eckhouse

The Office Action rejected claims 55-64 as being obvious under 35 USC 103 over Neev '438 in view of Eppstein et al. and Eckhouse et al. (US 5,885,273). More specifically, the Office Action alleged that Eckhouse taught the desirability of applying substances to an applicator portion of a device.

Applicant notes that claims 59, 60, and 62 have been cancelled without prejudice, so that claims 55-58, 61, and 63-64 remain of the claims subject to the rejection.

Applicant believes that the claims as amended are allowable over the proposed combination of Neev '438, Eppstein, and Eckhouse. As discussed previously with respect to the rejection of Neev '438 and Eppstein, the claims as amended are believed allowable because Neev '438 and Eppstein do not disclose, e.g., a pore expansion via application of thermal energy, a layer of rigid material, a resistive heater, etc. This is in contrast to the claims as amended.

Eckhouse is directed to hair removal by applying pulsed electromagnetic energy to the skin. This is in contrast to the claims as currently amended, which recite the application of thermal energy to the skin to expand pores. Applicant further believes that Eckhouse in no way suggests the use of a cap having a solid or rigid material therein for application to the skin. Instead, Eckhouse suggests the application of liquids to a device, with the liquids then applied to the skin via the device.

In view of the above, pending claims 55-58, 61, and 63-64 are believed allowable.

The New Claims

By this Amendment, new claims 70-85 have been added. The new claims are believed allowable over the cited art.

FEES DUES WITH THIS AMENDMENT

Excess Claims Fees:

Prior to this Amendment, a total of 33 claims, including 3 independent claims, were pending in the Application. With this Amendment, 31 total claims, including 4 independent claims, are pending in the Application. Accordingly, while there are 2 fewer total claims, there is 1 extra independent claim. Accordingly, an excess claims fee in the amount of \$110.00 is due. The appropriate payment is submitted herewith with the attached form SB17.

Two-Month Extension Fee:

A Request for Two-Month Extension is submitted herewith with the appropriate fee of \$245.00.

Request for Continued Examination (RCE):

A Request for Continued Examination is submitted herewith with the appropriate fee of \$405.00.

CONCLUSION

In view of the foregoing, it is submitted that all pending claims are now in condition for allowance. Hence an indication of allowability is hereby requested.

Applicant hereby requests an in-person interview the Examiner at the Examiner's convenience. Applicant will contact the Examiner via telephone to schedule such an interview. If direct communication with Applicants' attorney would serve to advance prosecution of this case, the Examiner is cordially requested to call the undersigned attorney at the below-listed telephone number.

Respectfully submitted,



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